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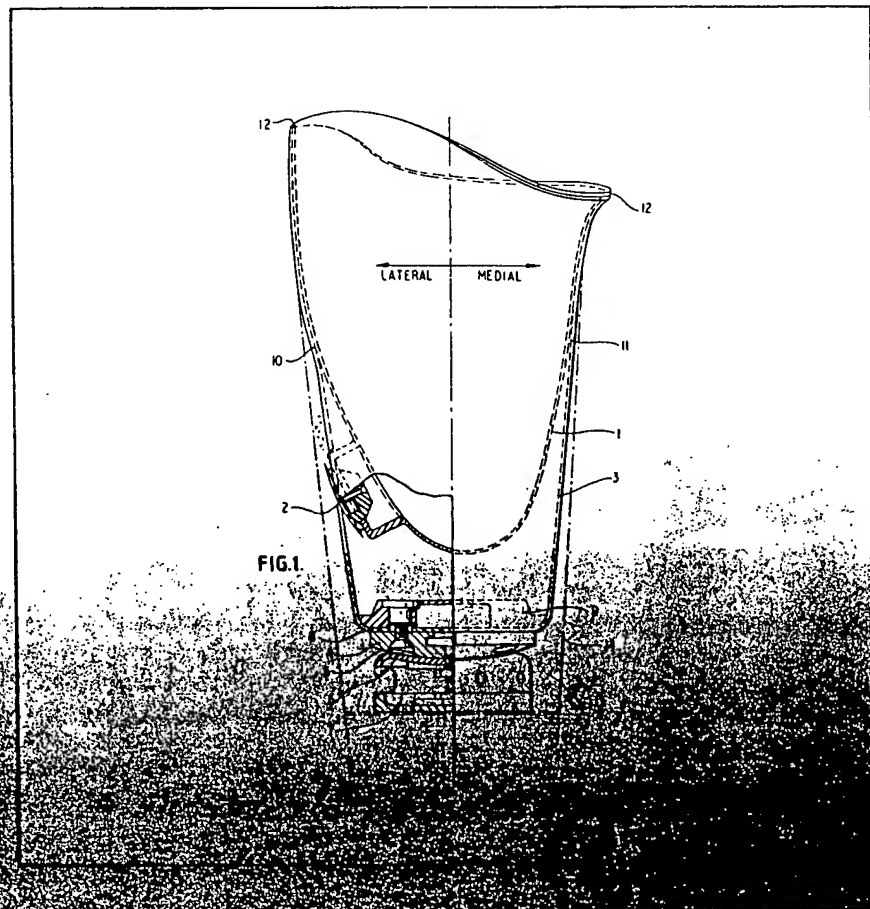
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Chas. A. Blatchford &
Sons Ltd.,
Lister Road,
Basingstoke,
Hants
(72) Inventors
Herbert Thompson,
John Jeffrey Shorter
(74) Agents
Withers & Rogers,
4 Dyer's Buildings,
Holborn,
London EC1N 2JT

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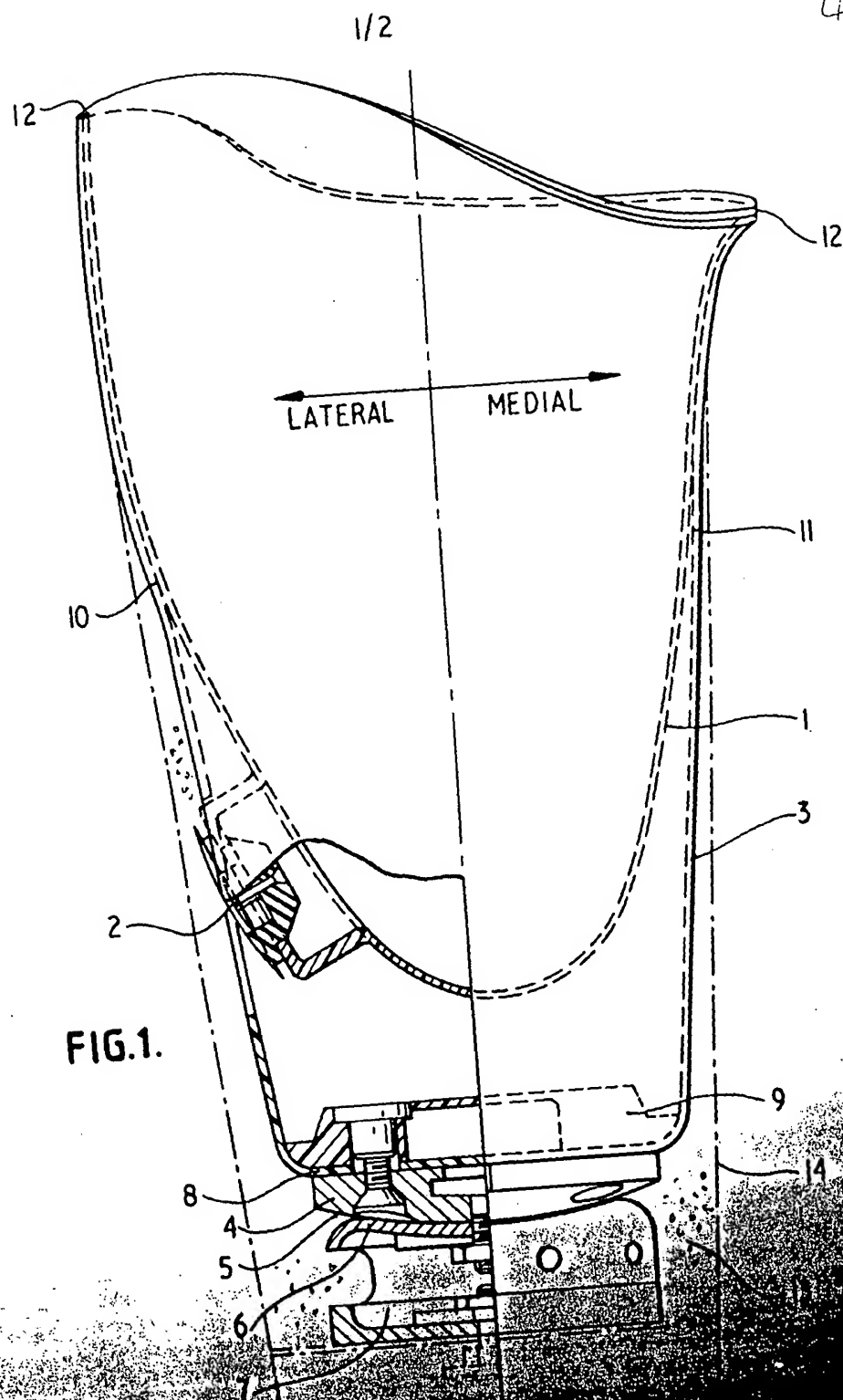
(57) An artificial limb with a thermoplastics stump socket (1) is attached to the remainder of the limb by a polypropylene socket container (3). A portion of the inner surface of the container (3) is shaped to correspond to the tapered shape of the socket (1) and is in intimate contact with the socket. No adhesive is required. The matching of the socket and the container shapes is achieved by using the socket as part of a mould for vacuum-forming the container. The container (3) provides a relatively lightweight connection between the socket (1) and an alignment coupling (4 to 7), whereas previously the space between these two components was occupied by relatively heavy metal tubing and associated connecting parts.

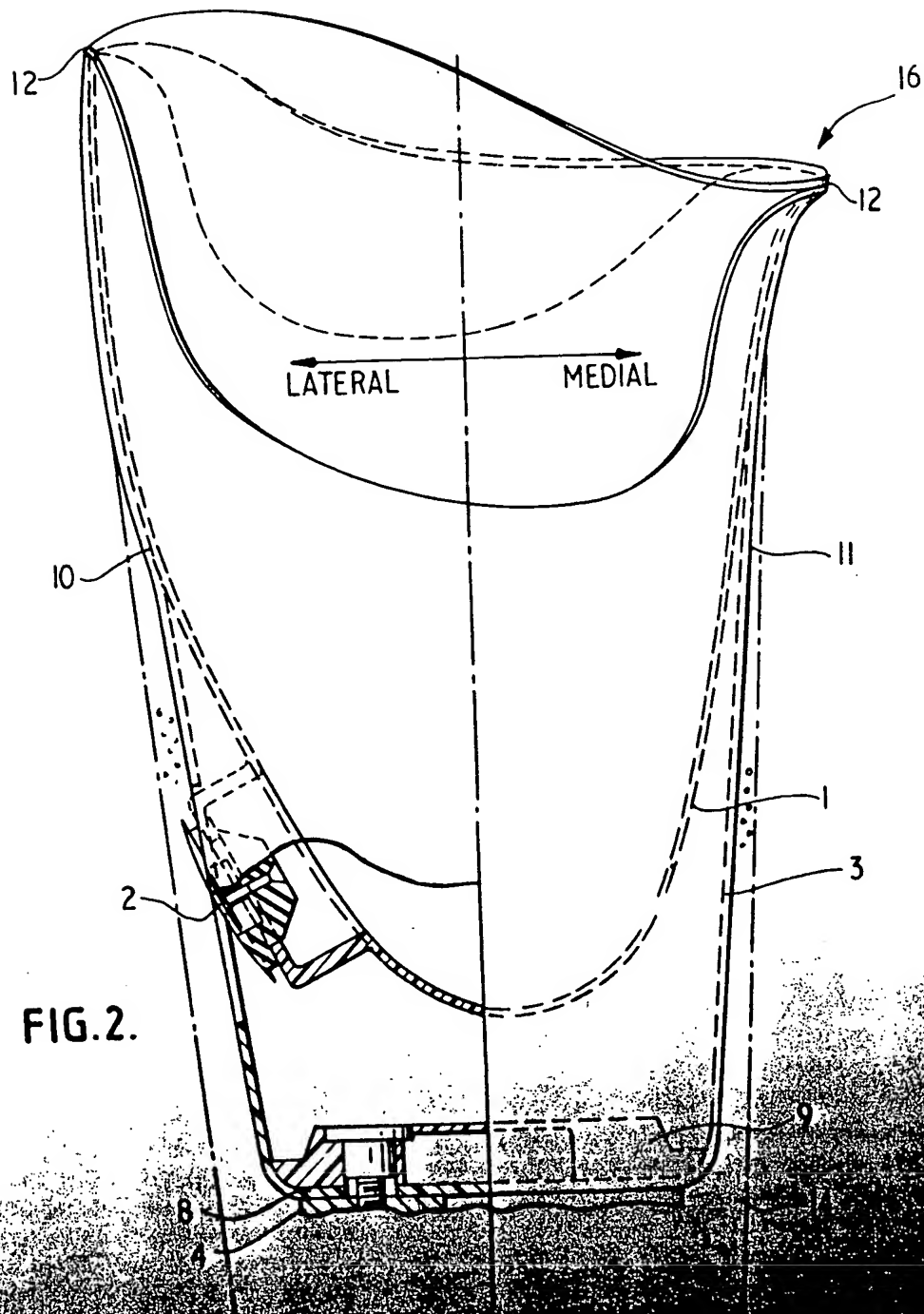


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SPECIFICATION

Improvements in artificial limbs

- 5 This invention relates to an artificial limb and to the attachment of an artificial limb socket to an artificial limb structure.

Until recently artificial limb sockets have normally been made of wood or metal, or moulded in a thermoplastic material. However techniques have now been developed whereby a socket for an artificial leg can be vacuum formed in a thermoplastics material, for example polypropylene, and in particular whereby the socket can be vacuum formed over a cast impression of the patient's stump. In addition, polypropylene is now being used in the manufacture of adjustable diameter sockets suitable mainly for temporary use by the patient while an individual socket for permanent use is being made up.

- 20 The development of the thermoplastics socket has given rise to difficulties in attaching the socket to the remainder of the artificial limb structure, since conventional attachment methods used with sockets made of other materials are not suitable, due particularly to the relative thinness of the thermoplastics socket wall and the lack of effective adhesives for use with some thermoplastic materials.

In the case of a thermoplastics above-knee socket for an artificial leg it is possible to attach a fixing plate, or other interfacing component, to the end of the socket by sandwiching the end portion of the socket between the interfacing component and a relatively rigid plate placed inside the socket, the interfacing component and the internal "trapping" plate being drawn together by one or more bolts passing through holes in the end of the socket. For a relatively long stump the interfacing component may be bolted directly to, for example, a known alignment coupling, or the interfacing component may itself form part of the alignment coupling. However, in the case of a shorter stump, an intermediate member such as a length of metal tubing must be used to connect the socket to the alignment coupling or artificial knee. This intermediate member and its connecting parts represent a significant proportion of the weight of the artificial leg above the knee, and in addition could impose undesirable stresses on the socket itself.

The present invention at least partly overcomes the above-mentioned disadvantages in that, according to one aspect of the invention, there is provided an artificial limb having a thermoplastics stump socket, wherein the socket is received in a thermoplastics socket container having an inner surface of which a portion is shaped to match the shape of the outer surface of the socket, and which portion engages the said outer surface. According to another aspect of the invention, there is provided a method of making an artificial limb having a thermoplastics stump socket, in which a thermoplastics socket container is moulded on an internal mould, which mould includes the socket or an impression thereof,

so that a portion of the inner surface of the container is shaped to match the shape of the outer surface of the socket. The container is preferably formed of polypropylene and is moulded by draping a heated sheet of the material over the mould and applying suction to the remaining space between the sheet and the mould. In this way a container may be produced which has an open end for receiving the socket and a closed end for attaching a endoskeletal limb structure. Where the container is shaped to match the outer surface of the socket, engagement between the container and socket is preferably by intimate contact of one surface with the other without any intervening material. The container may cover the whole outer surface of the socket with the rim of the container adjacent the rim of the socket, or in certain applications where greater flexibility is required, the container may be comparatively short so that the upper part of the socket wall is exposed between the rim of the container and the rim of the socket. In the latter case the container rim may be spaced from the socket rim around the whole socket, or alternatively the container may extend to the socket rim only at one or two points to provide extra support for longitudinally applied loads. The container rim may be heat-welded to the outer surface of the socket or to the socket rim.

Although the invention is applicable to different types of sockets, it is primarily intended for the attachment of an above-knee socket to a knee mechanism. An above-knee socket is normally tapered and has a flared rim, so that a container which is moulded to match the tapered outer surface of the socket is able to support longitudinal load on the artificial leg without additional means of fixing such as rivets between the socket and the container.

The lower closed end of the container may be attached to an interfacing component in a similar manner to that described above with reference to the attachment of a long stump socket to an artificial leg.

In the case of an artificial leg for a patient with an above-knee amputation, the container performs three main functions:-

- (i) it spaces the socket from the artificial knee by the required distance;
- (ii) it includes an interfacing component which may form part of an adjustable alignment coupling;

110 and

- (iii) by virtue of the fixed orientation of the interfacing component relative to the socket, it determines the static or initial build or bench alignment of an alignment coupling and/or knee mechanism relative to the socket. This alignment is chosen so that when the alignment coupling and the knee mechanism are later attached to the container, they are attached in a "neutral" position to make available the maximum range of adjustment in use of the alignment coupling.

In performing the first two functions, the container has the advantage that it is a single unit which can be attached to the socket and the knee mechanism, and which can be adjusted to the required position.

end, the container is a one-piece structure which mates directly with the socket. It is therefore relatively convenient and economical to manufacture.

It is a subsidiary feature of the invention that the closed end of the container can constitute part of an adjustable alignment coupling between the socket and the knee. The preferred embodiment has a metallic interfacing plate with a spherical convex lower surface which corresponds to the spherical concave surface of a known alignment coupling. However, as an alternative, the spherical convex surface may be moulded in the thermoplastics material of the container, eliminating the need for a separate metal interfacing component.

The container may be used with a suction socket which relies on a partial vacuum created between the socket and the stump to hold the socket and other attached artificial limb structure in place, or with other types of socket which, in the case of an artificial leg, are supported by an artificial hip joint connected to a pelvic band.

The invention will now be described by way of example with reference to the drawings in which:—

Fig. 1 is a partially sectioned anterior side view of a socket container, an above-knee suction socket, and an alignment coupling for attachment to a knee mechanism; and

Fig. 2 is a partially sectioned anterior side view corresponding to Fig. 1 in which the container does not extend over the whole outer surface of the socket.

Referring to Fig. 1, a socket 1 is a thin-walled thermoplastics socket individually moulded to match the patient's stump by vacuum forming over a cast of the stump. It is fitted with a known valve 2 which enables the socket to be retained on the stump by suction. A socket container 3 is formed with an open upper end for receiving the socket 1, and a closed lower end which has a metal end plate 4 with a convex spherical lower surface 5 corresponding to the concave spherical surface 6 of an alignment coupling member 7. The end plate 4 is attached by sandwiching the end wall 8 of the container between a rigid thermoplastics trapping plate 9 and the end plate 4. In this embodiment the upper wall of the container is in intimate contact with the socket from the locations 10 and 11 upwardly to the rim 12 of the socket, where the container top edge is edge-welded to the rim 12. The socket is generally tapered from the rim downwards. This contributes to the ability of the container to support the socket when under longitudinal load in particular; the edge weld serves mainly to locate the container and to prevent displacement of the container relative to the socket.

As a result of the taper on the socket, and the extent to which the container conforms to the outer surface of the socket, the container does not, in the illustrated embodiment at least, form the outer wall of the artificial limb, but it provides a base for a foam sleeve cosmesis 13 which envelops the lower part of the container and the alignment components 4 and 7. The cosmesis 13 has a washable PVC covering 14.

The container 3 is produced as follows:

The starting point is a vacuum formed thermoplastics socket 1 and one or more measurements are pro-

vided by the artificial limb fitter or prosthetist. Using a bench alignment fixture or jig the socket 1 is supported at the required orientation and distance above the knee mechanism and alignment coupling 7. The end plate 4, a packing piece to simulate the container wall, and a trapping plate 9 are also bolted in position on the coupling 7. The space between the socket 1 and the trapping plate 9 is then enclosed by, for example, a flexible polythene sheet formed into a tube and a liquid polyurethane mixture is flowed into the space which is then filled completely by the expanding foam. The diameter of the enclosed space is larger than the intended diameter of the container.

The polyurethane mixture produces a rigid foam mass forming an extension of the socket which supports the socket relative to the trapping plate when the assembly is removed from the jig. The end plate 4 is detached from the packing piece and the trapping plate 9, and the foam section is trimmed down to the required inner shape of the container, particular care being taken to remove foam from the upper part of the socket where the container is to be in close contact with the socket. The assembly of the trapping plate 9, the shaped foam section and the socket 1 constitute the mould over which the container is then vacuum formed.

When the container has cooled, it is slit from the rim downwards to enable the socket and the foam section to be removed. The trapping plate 9 remains in the closed end of the container. The end wall 8 of the container is drilled to allow the end plate 4 to be bolted to the trapping plate 9 and the socket 1 is replaced in the container. The edges of the slit in the container are then welded together and the top edge of the container is edge welded to the rim 12 of the socket. Alternatively, if it is anticipated that the container may in the future have to be removed from the socket, the welding steps above are omitted and the socket is secured in the container by one or more straps (not shown); across the slit.

As an alternative to forming the mould from polyurethane foam, plaster of paris may be used, or, to avoid the need to cut a slit in the container, the mould may instead be composed of a material which can be removed after vacuum forming by melting or dissolving. For instance a wax may be used in a process analogous to the "lost wax" method of casting metals. Only a small hole is needed to allow the mould material to escape from the container. As a further alternative, the mould material, if sufficiently light in weight, need not be removed at all. One example of such a material is polystyrene foam.

To improve the strength of the joint between the socket and the container the socket may have a ribbed outer surface before the container is formed, so that corresponding ribs are produced in the container.

A variation on the embodiment of Fig. 1 is illustrated in Fig. 2. One advantage of the embodiment of Fig. 2 is that the container 3 is formed over a known metal and thermoplastics socket 1, which the prosthetist can use to make measurements and provide the required orientation and distance above the knee mechanism and alignment coupling 7. The end plate 4, a packing piece to simulate the container wall, and a trapping plate 9 are also bolted in position on the coupling 7. The space between the socket 1 and the trapping plate 9 is then enclosed by, for example, a flexible polythene sheet formed into a tube and a liquid polyurethane mixture is flowed into the space which is then filled completely by the expanding foam. The diameter of the enclosed space is larger than the intended diameter of the container. The polyurethane mixture produces a rigid foam mass forming an extension of the socket which supports the socket relative to the trapping plate when the assembly is removed from the jig. The end plate 4 is detached from the packing piece and the trapping plate 9, and the foam section is trimmed down to the required inner shape of the container, particular care being taken to remove foam from the upper part of the socket where the container is to be in close contact with the socket. The assembly of the trapping plate 9, the shaped foam section and the socket 1 constitute the mould over which the container is then vacuum formed.

provided in the region of the tuber seating (indicated in the Figure by reference 16) where the rim 15 of the container 3 lies adjacent the rim 12 of the socket 1.

- 5 The rim 15 of the container also reaches the socket rim 12 on the lateral side to provide a relatively rigid area 17 for supporting a hip joint (not shown).

CLAIMS

1. An artificial limb having a thermoplastics stump socket, wherein the socket is received in a
- 10 thermoplastics socket container having an inner surface of which a portion is shaped to match the shape of the outer surface of the socket, and which portion engages the said outer surface.
2. An artificial limb according to claim 1 wherein
- 15 the container is moulded to correspond to, and is in intimate contact with, a tapered outer surface portion of the socket.
3. An artificial limb according to claim 1 or claim 2 wherein the container encloses at least a closed
- 20 end portion of the socket and extends beyond the end of the socket to an outer end portion which is attached to a distal limb structure portion.
4. An artificial limb according to claim 3 wherein the outer end portion of the container has a trans-
- 25 versely extending end wall spaced from the end of the socket and clamped between a trapping member inside the container and a rigid mounting surface of the said limb structure.
5. An artificial limb according to claim 3 or claim
- 30 4 wherein the outer end portion is attached to an adjustable alignment coupling.
6. An artificial limb according to any preceding claim, wherein the container has a rim which, over at
- 35 least part of its length, lies adjacent the rim of the socket.
7. An artificial limb according to claim 6 wherein at least part of the container rim is heat-welded to the socket.
8. An artificial limb according to claim 6 or claim
- 40 7 for an above-knee amputee, wherein the socket has an open end portion which is flared to provide a tuber seating, and wherein the container rim, over at least a first portion of its length, is spaced from the socket rim to expose part of the socket outer surface,
- 45 but over a second portion of its length lies adjacent to the socket rim in the region of the tuber seating to provide support for loads applied longitudinally of the socket.

9. An artificial limb according to claim 6, claim 7,
- 50 or claim 8 for an above-knee amputee, wherein the container extends substantially to the socket rim on the lateral side of the socket to provide a mounting area for a hip joint member.

10. An artificial limb according to any preceding
- 55 claim, wherein the socket includes a suction valve.

11. A method of making an artificial limb having a thermoplastics stump socket, in which a thermoplastics socket container is moulded on an internal
- 60 mould, which mould includes the socket or an impression thereof, so that a portion of the inner surface of the container is shaped to match the shape of the outer surface of the socket.

12. A method according to claim 11, wherein the container is vacuum-formed on the internal mould.

- 85 13. A method according to claim 11 or claim 12

wherein the mould is produced by forming an extension on an end portion of the socket.

14. A method of making an artificial limb comprising the steps of:-

- 70 (i) providing a thermoplastics stump socket which is moulded using an impression of the patient's stump, the socket having a closed end and an open end;
- (ii) supporting the socket in a jig and forming an
- 75 extension on the closed end of the socket so as to produce a socket container mould comprising the socket and the extension, the extension having an end surface defining the orientation of the socket in the artificial limb; and
- 80 (iii) removing the combination of the socket and the extension from the jig and moulding a thermoplastics socket container over the combination so that a portion of the inner surface of the container is shaped to match the shape of the outer surface of
- 85 the socket, the said inner surface portion engaging the socket outer surface.

15. An artificial limb including a thermoplastics stump socket, having an open end and a closed end, and a thermoplastics socket container having an
- 90 open end and a closed end, wherein the inner surface of the container is shaped, over at least a portion of its area, to match the outer surface of the socket, the socket being received in the open end of the container with the said inner surface portion of the container engaging the outer surface of the socket, and with the container enclosing a space between its closed end and the closed end of the socket.

16. An artificial limb constructed and arranged substantially as herein described and shown in the
- 100 drawings.

17. A method of making an artificial limb substantially as herein described with reference to the drawings.

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